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M.K.

18N1/0922

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ART UNIT PAPER NUMBER
24

1813

DATE MAILED: 09/22/93

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined

☒ Responsive to communication filed on

☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐

Part II SUMMARY OF ACTION

1. ☒ Claims 1, 2, 9, 11-13, 15-18 and 20 are pending in the application.
Of the above, claims are withdrawn from consideration.
2. ☒ Claims 3-7, 10, 14 and 19 have been cancelled.
3. ☐ Claims are allowed.
4. ☒ Claims 1, 2, 9, 11-13, 15-18 and 20 are rejected.
5. ☐ Claims are objected to.
6. ☐ Claims are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. ; filed on
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

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EXAMINER'S ACTION

Art Unit 1813

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1813.

Applicant's amendments and arguments filed May 13, 1993, Declarations by Dr. Weiner filed May 18, 1993 have been carefully considered and are sufficient to overcome the rejection under 35 USC 112, second paragraph against claims. Further the rejection under 35 USC 102/103 against claim 19 is moot since the claim has been cancelled.

However, the specification remains objected to and claims remain rejected as set forth below.

Making particular references to the parent applications and updating the status of the parent application at the first line of the specification is required.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 120 as follows:

The continuing application must contain a specific reference to the parent application(s) in the specification.

The disclosure is objected to because of the following informalities: "MPB" occurs at page 19 in the legend to Table III.

Further, Applicant's attention is drawn to the fact that claim 20 was never requested to be added. The claim newly appears as claim "21 (amended)" in the amendment filed 8/31/92. Appropriate correction to indicate that the claim 20 is "once amended" as in the amendment filed May 13, 1993 and not "twice amended" is suggested. Appropriate

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correction is required.

The specification ^{main} remaining objected to and claims 1, 2, 9, 11-13, 15-18 and 20 remain rejected under 35 USC 112, first paragraph and under 35 USC 101 for the reasons previously set forth in the prior Office actions.

Applicant urges at pages 4-5 that the declaration filed May 18, 1993 provides the operability and utility of the instant invention. However, Applicant's attention is drawn to the fact that the showing is not commensurate with claimed invention.

Further, the specification as originally filed does not provide the conditions and parameters that would yield successful practice with human. It is unclear what Applicant considers "the dosages were determined through empirical extrapolation of those used in animal studies". For instance, the declaration uses 300 mg capsules of MBP (bovine) per day per person. The specification on the other hand uses 25 μ g, 100 μ g and 500 μ g MBP at 14 and 7 days before induction of EAE in Lewis Rats (Table 1 on page 16); administered 0.5 mg MBP 7.5 and 2 days before or after induction EAE (Table II, on page 18) or before and after or before or after (Table III on page 19) with 0.1 mg and the persistence of oral tolerance tested with 0.5mg (Table II) were challenged with 50 μ g MBP in CFA up to 56 days after induction of EAE (Table IV on page 20). Four peptides and MBP bovine of varying amounts were tested in Table V on page 21 to determine the efficacy of prevention of clinical incidence of EAE.

The protocol used in the specification cannot be translated to effective parameters to

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human studies in view of the art recognized conflicting findings and/or unpredictability. It is noted that depending on the amounts of antigens administered, the same antigen elicits immune response or suppresses the immune response or cause autoimmune diseases.

As such, the data presented in the declaration is encouraging for the efficacy of use of MBP in human, but such are not commensurate in scope as originally filed.

Claims 1, 2, 9, 11-13, 15-18 and 20 remain rejected under 35 USC 103 over Campbell et al in view of Whitacre et al and/or Nagler-Anderson et al set forth in the prior Office action.

Applicant urges at pages 6-11 of the amendment that Campbell's teachings are totally different than oral tolerance and because the difference in mode of administration between the teaching to the secondary references Whitacre et al and Nagler-Anderson et al, the secondary references cannot be used to modify the teachings of Campbell.

However, Applicant's attention is drawn to the fact that all of the references teach tolerance irrespective of routes using the autoantigens.

Further, Applicant at pages 9-10 section B of amendment urges that Whitacre administers MBP with STI and that the authors later articles further define the mechanism of action. However, the teachings relied on are as of the filing date of the instant application and as such the reference positively provides motivation for the use of MBP in human.

Further, Applicant's attention is drawn to the fact that the instant claims do not exclude the use of STI.

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Applicant at section B on pages 10 and 11 of the amendment urges that Nagler-Anderson provides no basis the results it describes could be extrapolated to humans because was not capable of adoptively transferring protection.

However, the reference teaches that oral tolerance occurs using T-dependent antigens and it was known that intravenous administration of autoantigen such as collagen was effective to suppress induction of arthritis. See page 7443 of Nagler-Anderson.

Applicant's contention that Campbell's regime is ineffective or that the mechanism is via anergy is not persuasive because the instant claims do not recite active T-cell suppression and read on anergy and the reference relied on reports of optimistic data.

Therefore, Applicant's arguments and declaration are not deemed persuasive.

Claims 1, 9, and 11-12 remain provisionally rejected since a terminal disclaimer has not been made of record.

Applicant believes such "a rejection is premature". See page 12 of amendment. Applicant's attention is drawn to the fact it was a "*provisional*" rejection and the basis for the provisional rejection was stated to be because the conflicting claims have not in fact been patented.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED

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STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax center number is (703) 308-4227 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kay K. Kim Ph.D. whose telephone number is (703) 308-3881.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Kim/tf
September 21, 1993


KAY-K. KIM
PRIMARY EXAMINER
GROUP 1800

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